



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Daniel J. Benedict

Confirmation No.: 9818

Group Art Unit: 1651

Serial No.: 10/056,662

Examiner: Leon B. Lankford, Jr.

Filed: 01/23/2002

Docket No.: 140205-1010

For: **Method and Apparatus for Islet Isolation**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

This information disclosure statement is filed in accordance with 37 C.F.R. §§ 1.56, 1.97, and 1.98, and specifically:

- ☒ under 37 CFR 1.97(b), or  
(within Three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- ☐ under 37 CFR 1.97(c) together with either a:  
☐ Statement Under 37 C.F.R. 1.97(e), or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the CFR 1.97(b) time period, but before the final office action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with a:  
☐ Statement under 37 CFR 1.97(e), and  
☐ a \$180.00 petition fee set forth in 37 CFR 1.17(p).  
(Filed after final office action or notice of allowance, whichever occurs first, but before payment of the issue fee)

Enclosed is a check in the amount of \$

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Please charge \$ to deposit account . At any time during the pendency of this application, please charge any fees required to Deposit Account pursuant to 37 CFR 1.25. The Commissioner is hereby requested to credit any overpayment to Deposit Account No.

- ☒ Applicant(s) submit herewith *Form PTO 1449A - Information Disclosure Statement by Applicant* together with copies (where required) of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may or may not be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56. As required by 37 C.F.R. §1.98(a), a legible copy of each document is provided.
- ☐ A concise explanation of the relevance of foreign language patents, foreign language publications and other foreign language information listed on PTO Form 1449, as presently understood by the individual(s) designated in 37 CFR 1.56(c) most knowledgeable about the content is given on the attached sheet, or where a foreign language patent is cited in a search report or other action by a foreign patent office in a counterpart foreign application, an English language version of the search report or action which indicates the degree of relevance found by the foreign office is listed on the form PTO 1449 and is enclosed herewith.

The following rights are reserved by the Applicant(s): the right to establish the patentability of the claimed invention over any of the listed documents should they be applied as reference, and/or the right to prove that some of these documents may not be prior art, and/or the right to prove that some of these documents may not be enabling for the teachings they purport to offer.

This statement should not be construed as a representation that an exhaustive search has been made, or that information more material to the examination of the present application does not exist. Any statements or identifications regarding the relevance of any portion(s) of cited references should not be construed as a representation that the most relevant portion(s) have been identified, and the absence of such statements or identifications should not be construed as representations that there are no relevant portion(s). The Examiner is specifically requested not to rely solely on the materials submitted herewith. The Examiner is requested to conduct an independent and thorough review of the documents, and to form independent opinions as to their significance.

It is requested that the information disclosed herein be made of record in this application and that the Examiner initial and return a copy of the enclosed PTO-1449 to indicate the documents have been considered.

Respectfully Submitted,

THOMAS, KAYDEN, HORSTEMEYER  
& RISLEY, L.L.P.

By:

  
N. Andrew Crain, Reg. No. 45,442

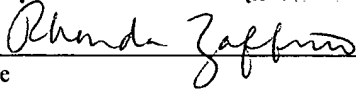


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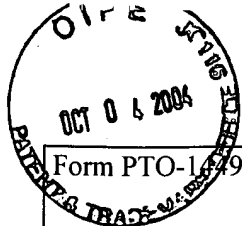
**CERTIFIED MAILING**

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Form PTO-1579

**INFORMATION DISCLOSURE CITATION***(Use several sheets if necessary)*Attorney Docket No.  
**140205-1010**Serial No.  
**10/056,662**Applicant  
**Daniel J. Benedict**Filing Date  
**01/23/2002**Group  
**1651****U.S. PATENT DOCUMENTS**

Examiner Initials	Item	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	A	4,868,121	9/19/1989	Scharp et al.	435	268	9/9/1985
	B	5,079,160	1/7/1992	Lacy et al.	435	240.2	6/8/1987
	C	5,322,790	6/21/1994	Scharp et al.	435	268	6/9/1989
	D	5,834,005	11/10/1998	Usala	424	424	12/7/1995
	E	5,837,738	11/17/1998	Williamson et al.	514	634	2/5/1997
	F	5,853,976	12/29/1998	Hesse et al.	435	4	12/20/1995
	G	5,879,939	3/9/1999	Gray et al.	435	379	5/17/1995
	H	5,919,703	7/6/1999	Mullen et al.	435	381	6/6/1996
	I	5,919,775	7/6/1999	Amin et al.	514	152	4/16/1998
	J	5,952,215	9/14/1999	Dwulet et al.	435	220	11/2/1998

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)**

	K	Bond, M.D. and Van Wart, H.E., "Purification and Separation of Individual Collagenases of <i>Clostridium histolyticum</i> Using Red Dye Ligand Chromatography," <i>Biochemistry</i> 1984; 23:3077-3085
	L	Bond, M.D. and Van Wart, H.E., "Characterization of the Individual Collagenases from <i>Clostridium histolyticum</i> ," <i>Biochemistry</i> 1984; 23:3085-3091
	M	Scharp, D.W., "Isolation and Transplantation of Islet Tissue," <i>World Journal of Surgery</i> 1984; 8:143-151
	N	Eckhardt, T., Jahr, H., Federlin, K. and Bretzel, R.G., "Endotoxin impairs the engraftment of rat islets transplanted beneath the kidney capsule of C57BL/6-mice," <i>Journal of Molecular Medicine</i> 1999; 77:123-125
	O	Jahr, H., Pfeiffer, G., Hering, B.J., Federlin, K., and Bretzel, R.G., "Endotoxin-mediated activation of cytokine production in human PBMCs by collagenase and Ficoll," <i>Journal of Molecular Medicine</i> 1999; 77:118-120
	P	Linetsky, E., Inverardi, L., Kenyon, N.S., Alejandro, R., and Ricordi, C., "Endotoxin Contamination of Reagents Used During Isolation and Purification of Human Pancreatic Islets," <i>Transplantation Proceedings</i> 1998; 30:345-346
	Q	Smith, Jr., G.N., Brandt, K.D., and Hasty, K.A., "Procollagenase Is Reduced to Inactive Fragments upon Activation in the Presence of Doxycycline," <i>Annals New York Academy of Sciences</i> 1994; 732:436-438
	R	Vargas, F., Vives-Pi, M., Somoza, N., Armengol, P., Alcalde, L., Marti, M., Costa, M., Serradell, L., Dominguea, O., Fernandez-Llamazares, J., Julian, J.F., Sanmarti, A., and Pujol-Borrell, R., "Endotoxin Contamination May Be Responsible for the Unexplained Failure of Human Pancreatic Islet Transplantation," <i>Transplantation</i> 1998; 65(5):722-727

\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

EXAMINER'S SIGNATURE:

DATE CONSIDERED: